AMENDMENTS TO THE CLAIMS

Applicant has submitted a new complete claim set. This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) A method for treating a patient with a symptom of constipation-predominant irritable bowel syndrome comprising administering to [[a]] the patient ~~in need of such treatment~~ an amount of a pharmaceutical preparation comprising methylnaltrexone effective to ameliorate ~~at least one~~ the symptom ~~of the irritable bowel syndrome~~.

2. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered parenterally.

3. (Canceled)

4. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered intravenously.

5. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered subcutaneously.

6. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered via a needleless injection.

7. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered via an infusion.

8. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered intrarectally.

9. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered transdermally.

10. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered intranasally.

11. (Original) The method of claim 1 wherein the pharmaceutical preparation is administered as a solution.

12. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered as a suppository.

13. (Withdrawn) The method of claim 1 wherein the pharmaceutical preparation is administered as an enema.

14. (Original) The method of claim 1 wherein the pharmaceutical preparation is administered as a tablet or capsule.

15. (Original) The method of claim 1 wherein the patient is not undergoing exogenous opioid treatment.

16. (Original) The method of claim 1 wherein the patient is female.

17. (Original) The method of claim 1 wherein the patient is male.

18. (Original) The method of claim 1 wherein the patient is a child.

19-20. (Canceled)

21. (Original) The method of claim 1 wherein the symptom is constipation.

22. (Original) The method of claim 1 wherein the symptom is constipation and abdominal pain.

23. (Original) The method of claim 1 wherein the symptom is abdominal bloating.

24. (Original) The method of claim 1 wherein the symptom is abdominal distension.

25. (Original) The method of claim 1 wherein the symptom is abnormal stool frequency.

26. (Original) The method of claim 1 wherein the symptom is abnormal stool consistency.

27. (Original) The method of claim 1 wherein the symptom is abdominal pain.

28. (Original) The method of claim 1 further comprising administering an antibiotic to the patient.

29. (Original) The method of claim 1 further comprising administering an opioid agonist to the patient.

30. (Original) The method of claim 1 further comprising administering at least one irritable bowel syndrome therapeutic agent to the patient.

31. (Original) The method of claim 30, further comprising administering an opioid agonist to the patient.

32. (Currently amended) The method of claim 30, wherein the irritable bowel syndrome therapeutic agent is selected from the group consisting of ~~antispasmodics, anti-muscarinics,~~ antiinflammatory agents, pro-motility agents, ~~$5HT_1$ agonists, $5HT_3$ antagonists,~~ $5HT_4$ antagonists, $5HT_4$ agonists, ~~bile salt sequestering agents,~~ bulk-forming agents, ~~alpha2-adrenergic agonists,~~ mineral oils, antidepressants, herbal medicines, and combinations thereof.

33. (Withdrawn) The method of claim 30, wherein the irritable bowel syndrome agent is not a $5HT_3$ antagonist, a $5HT_4$ antagonist, or a $5HT_4$ agonist.

34. (Canceled)

35. (Withdrawn) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

36. (Withdrawn) The method of claim 30 wherein the irritable bowel syndrome therapeutic agent is an herbal medicine.

37. (Canceled)

38. (Original) The method of claim 30 wherein the agent is a $5HT_4$ agonist.

39. (Previously presented) The method of claim 38, wherein the $5HT_4$ agonist is 3-(5-methoxy-indole-3-yl-methylene)-N-pentylcarbazimidamide.

40. (Withdrawn) The method of claim 30 wherein the agent is polyethylene glycol 3350.

41-42. (Canceled)

43. (Previously presented) The method of claim 1 wherein the amount of methylnaltrexone ranges from 1.0 to 3.0 mg/kg.

44. (Canceled)

45. (Previously presented) The method of claim 1 wherein the amount of methylnaltrexone ranges from 0.1 to 0.45 mg/kg.

46-47. (Canceled)

48. (Withdrawn) The method of claim 1 wherein the amount of methylnaltrexone is effective to achieve a mean peak plasma concentration of 1400 ng/ml or less.

49. (Withdrawn) The method of claim 48 wherein the amount of methylnaltrexone is effective to achieve a mean peak plasma concentration of 1200 ng/ml or less.

50. (Withdrawn) The method of claim 49 wherein the amount of methylnaltrexone is effective to achieve a mean peak plasma concentration of 1000 ng/ml or less.

51. (Currently amended) A method for treating a patient with a symptom of constipation-predominant irritable bowel syndrome comprising orally administering to [[a]] the patient ~~in need of such treatment~~ an amount of a pharmaceutical preparation comprising methylnaltrexone effective to ameliorate ~~at least one~~ the symptom ~~of the irritable bowel syndrome~~.

52. (Original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in an enteric coated formulation.

53. (Original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in a sustained release formulation.

54. (Original) The method of any one of claim 51 wherein the pharmaceutical preparation is administered in an enteric coated sustained release formulation.

55. (Original) The method of any of one claim 51 wherein the pharmaceutical preparation is administered in a colonic site-directed formulation.

56. (Original) The method of claim 51 wherein the patient is not undergoing exogenous opioid treatment.

57. (Original) The method of claim 51 wherein the patient is female.

58. (Original) The method of claim 51 wherein the patient is male.

59. (Original) The method of claim 51 wherein the patient is a child.

60. (Original) The method of claim 51 wherein the symptom is constipation.

61. (Original) The method of claim 51 wherein the symptom is constipation and abdominal pain.

62-63. (Canceled)

64. (Original) The method of claim 51 wherein the symptom is abdominal bloating.

65. (Original) The method of claim 51 wherein the symptom is abdominal distension.

66. (Original) The method of claim 51 wherein the symptom is abnormal stool frequency.

67. (Original) The method of claim 51 wherein the symptom is abnormal stool consistency.

68. (Original) The method of claim 51 wherein the symptom is abdominal pain.

69. (Original) The method of claim 51 further comprising administering an antibiotic to the patient.

70. (Original) The method of claim 51 further comprising administering at least one irritable bowel syndrome therapeutic agent.

71. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

72. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is an antidiarrheal medication.

73. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is a herbal medicine.

74. (Withdrawn) The method of claim 51 wherein the pharmaceutical preparation further comprises an opioid agonist.

75. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is an alpha$_2$-adrenergic agonist.

76. (Previously presented) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is a 5-HT$_4$ agonist.

77. (Previously presented) The method of claim 76 wherein the 5-HT$_4$ agonist is 3-(5-methoxy-indole-3-yl-methylene)-N-pentylcarbazimidamide.

78. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is not a 5-HT$_3$ antagonist, a 5-HT$_4$ antagonist or a 5-HT$_4$ agonist.

79. (Withdrawn) The method of claim 115 wherein the irritable bowel syndrome therapeutic agent is a polyethylene glycol 3350.

80-81. (Canceled)

82. (Previously presented) The method of claim 51 wherein the amount of methylnaltrexone ranges from 50 to 750 mg/day.

83. (Previously presented) The method of claim 82 wherein the amount of methylnaltrexone is 75 mg.

84. (Previously presented) The method of claim 51 wherein the amount of methylnaltrexone is 225 mg.

85. (Previously presented) A pharmaceutical preparation comprising methylnaltrexone, an irritable bowel syndrome therapeutic agent and a pharmaceutically acceptable carrier.

86-87. (Canceled)

88. (Currently amended) The pharmaceutical preparation of claim 85 wherein the irritable bowel syndrome therapeutic agent is selected from the group consisting of ~~antispasmodics, anti-muscarinics,~~ antiinflammatory agents, pro-motility agents, $5HT_1$ agonists, ~~$5HT_3$ antagonists, $5HT_4$ antagonists,~~ $5HT_4$ agonists, ~~bile salt sequestering agents,~~ bulk-forming agents, ~~alpha$_2$ adrenergic agonists,~~ mineral oils, antidepressants, herbal medicines and combinations thereof.

89-90. (Canceled)

91. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is an antiinflammatory agent.

92. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is a pro-motility agent.

93. (Withdrawn - Currently amended) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is a ~~$5HT_1$ agonist, a $5HT_3$ antagonist or a~~ $5HT_4$ agonist.

94. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is not a $5HT_3$ antagonist, a $5HT_4$ antagonist or a $5HT_4$ agonist.

95. ((Previously presented) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is a $5HT_4$ agonist.

96. ((Previously presented) The pharmaceutical preparation of claim 95 wherein the irritable bowel syndrome therapeutic agent is 3-(5-methoxy-indole-3-yl-methylene)-N-pentylcarbazimidamide.

97. (Canceled).

98. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is a bulk-forming agent.

99. (Canceled).

100. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is a mineral oil.

101. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is an antidepressant.

102. (Withdrawn) The pharmaceutical preparation of claim 88 wherein the irritable bowel syndrome therapeutic agent is an herbal medicine.

103. (Previously presented) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for oral administration.

104. (Previously presented) The pharmaceutical preparation of claim 103 wherein the formulation is selected from the group consisting of a capsule, a powder, a granule, a crystal, a tablet, a solution, an extract, a suspension, a soup, a syrup, an elixir, a tea, a liquid-filled capsule, an oil, a chewable tablet, a chewable piece, an enteric-coated tablet, a sustained release tablet or capsule, and an enteric-coated sustained release tablet.

105. (Withdrawn) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for rectal administration.

106. (Withdrawn) The pharmaceutical preparation of claim 105 wherein the formulation is selected from the group consisting of a suspension, a solution, a suppository, an oil, and an enema.

107. (Previously presented) The pharmaceutical preparation of claim 85 wherein the pharmaceutical preparation is formulated for a route of administration selected from the group consisting of sublingual, intranasal, transdermal, intradermal, intramuscular, subcutaneous, injectable, and infusion.

108. (Previously presented) A kit comprising:

a package containing methylnaltrexone,

an irritable bowel syndrome therapeutic agent; and

instructions for treating irritable bowel syndrome.

109. (Original) The kit of claim 108, further comprising an antibiotic.

110-111. (Canceled)

112. (Previously presented) The method of claim 38 wherein the $5HT_4$ agonist is tegaserod maleate.

113. (Previously presented) The method of claim 76 wherein the $5HT_4$ agonist is tegaserod maleate.

114. (Previously presented) The pharmaceutical preparation of claim 95 wherein the irritable bowel syndrome therapeutic agent is tegaserod maleate.

115. (Currently amended) The method of claim 70, wherein the irritable bowel syndrome therapeutic agent is selected from the group consisting of ~~antispasmodics, antidiarrheal medications, anti-muscarinics,~~ anti-inflammatory agents, pro-motility agents, $5HT_1$ agonists, ~~$5HT_3$ antagonists, $5HT_4$ antagonists,~~ $5HT_4$ agonists, ~~bile salt sequestering agents,~~ bulk-forming agents, ~~alpha2-adrenergic agonists,~~ mineral oils, polyethylene glycol 3350, antidepressants, herbal medicines, and combinations thereof.

116. (Previously presented) The pharmaceutical preparation of any of claims 1, 51, 85 or 108, wherein the pharmaceutical preparation is free of calcium or salts thereof.

117. (Previously presented) The pharmaceutical preparation of claim 116, wherein calcium, including ions thereof, is present in a concentration of less than 0.5%.

118. (Previously presented) The pharmaceutical preparation of claim 117, wherein calcium, including ions thereof, is present in a concentration of less than 0.1%.

119. (Previously presented) The pharmaceutical preparation of claim 118, wherein calcium, including ions thereof, is present in a concentration of less than 0.01%.

120. (Previously presented) The pharmaceutical preparation of claim 119, wherein there is no detectable level of calcium present.

121. (Currently amended) The pharmaceutical preparation of any of claims [[116-]] 117, 118, 119 or 120, wherein the preparation is an aqueous formulation comprising a chelating agent.